REMARKS

The Office Action of May 5, 2003 has been reviewed and the Examiner's comments carefully considered. Claims 28, 29, 32-35 and 47-49 are currently pending in the application. Claim 49 is cancelled. Claims 28, 29, 33, 47 and 48 are amended. New claims 50-52 are added. In claims 28, 33, 47, 48 and 50-52 support for the language "ATG at position 481 to 483 of said nucleic acid sequence" is found on page 40, line 18, support for the language "can be used to diagnose cells having a non-physiological proliferative capacity" is found on page 8, lines 13-15, support for the language "the promoter region of the CTNNB1 gene" is found on page 48, lines 32-34, and support for the language "fragment" is found on page 10, line 30. No new matter has been added. In view of these amendments and the following explanation, Applicant believes that all the asserted rejections are in condition for withdrawal and all the claims are in condition for allowance.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The present Amendment amends the specification to delete the embedded hyperlink.

Claims 28, 29, 32-35 and 47-49 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted indefiniteness. The Examiner asserts that it is not clear whether or not the 25% that is not identical to a polypeptide sequence of PLAG1 in the region from zinc fingers 4 to 7 alters the function of the protein. The Examiner further asserts that claim 28 still does not contain specific functional language.

By means of this Amendment, the Examiner will appreciate that all of the above §112 issues have been resolved. Claim 49 has been cancelled and independent claims 28 and 33 have been amended to recite an isolated nucleic acid comprised of a sequence that encodes a PLAG1 protein translated from the nucleic acid sequence represented in SEQ ID NO: 116 starting with the ATG at position 481 to 483, wherein the isolated nucleic acid can be used to diagnose cells having a non-physiological proliferative capacity. Claim 48 has been amended to recite a macromolecule comprised of a nucleic acid in isolated form with a sequence encoding the promoter region of a CTNNB1 gene which can be used to diagnose cells having a non-physiological proliferative activity. Claims 28, 33, 47 and 48 as amended, therefore, contain specific functional language for the isolated nucleic acids of the present

invention. Moreover, the newly recited functional language clearly defines which specific isolated nucleic acids fall within the scope of the claimed invention and which non-specific nucleic acids do not, especially because the language pertaining to 75% homology has been removed. Applicants submit that the above-delineated specific description of the present invention, as now more particularly claimed in independent claims 28, 33 and 48, fully satisfies the definiteness requirement and that the 35 U.S.C. § 112, second paragraph rejection is in condition for withdrawal.

Claims 28-29, 32-35, and 47-49 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of a written description. Claims 28, 29 and 47 have been amended, and new claims 50-52 have been added. Applicants submit that there is more than adequate written description of the PLAG1 fragments set forth therein to support all of these claims. In particular, the Examiner is directed to page 40, lines 20-23, and lines 33-38, wherein it is described that PLAG1 is composed of seven canonical C2H2 zinc finger domains with specific linker sequences in between, a non-finger C terminus of 259 amino acids which is serine-rich, and an N-terminal region containing two nuclear localization signals, see SEQ ID NOs: 117 to 124, which can be used to diagnose cancer cells, i.e., to diagnose cells having a non-physiological proliferative capacity, specifically. For example, more than adequate written description is provided for new claim 51 on page 42, line 31 spanning to page 43, line 13 and page 43, line 26 spanning to page 44, line 26, wherein several PCR products are described which are composed of PLAG1 and CTNNB1 sequences which again demonstrate, and exemplify, that fragments of CTNNB1 (and also of PLAG1) can be used to diagnose cells having a non-physiological proliferative capacity. Indeed, several PCR products are described specifically composed of PLAG1 and CTNNB1 exons. Thus, because the CTNNB1 gene is known, and the number of exons comprised in the gene are thus defined, Applicants believe that the number of nucleic acids encompassed by amended claim 47 and new claims 50-52 is well defined.

Additionally, Applicants have herewith amended claims 28, 33 and 48 to claim an isolated nucleic acid comprised of a sequence that encodes a PLAG1 protein translated from the nucleic acid sequence represented in SEQ ID NO: 116 starting with the ATG at position 481 to 483, wherein the isolated nucleic acid can be used to diagnose cells

having a non-physiological proliferative capacity. Not only are several PCR products described in the specification which are composed of PLAG1 and CTNNB1 sequences which demonstrate that PLAG 1 fragments may be used to diagnose cells having a non-physiological proliferative capacity, the Examiner has already acknowledged, at page 7, lines 6-7 of the Office Action, that that there is adequate written description of SEQ ID NO: 116 which is recognized as having a specific diagnostic function. Moreover, notwithstanding Applicants' discovery that PLAG1 fragments, as recited in amended claim 47, may include the sequences represented in SEQ ID NOs: 117 to 123, Applicants also have discovered at page 5, lines 1-3, that the significance of SEQ ID NO: 116 is even broader still. Applicants disclose that PLAG1 breaks occurring outside the actual genes but in the vicinity thereof result in aberrant growth, so that one skilled in the art will always be able to practice the invention when using at least the claimed nucleic acid sequence corresponding to SEQ ID NO: 116, or a fragment thereof, which SEQ ID NO: 116 is the common denominator of all of the embodiments of the present invention. Therefore, based on the above, as well as because the promoter region of the CTNNB1 gene is known, as set forth in amended claim 48, Applicants submit that the number of nucleic acids embraced by the language of newly amended claims 28, 33, 47 and 48 is well defined and adequately satisfies the written description requirement.

For all the foregoing reasons, amended claims 28, 29, 33, 47, 48 and new claims 50-52 are now in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 28, 29, 32-35, 47, 48, and 50-52 is respectfully requested.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By _____

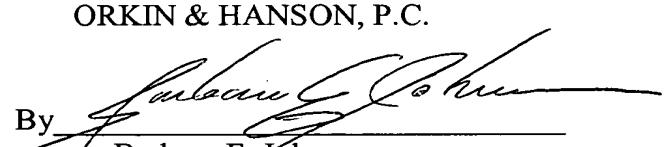
Barbara E. Johnson
Registration No. 31,198
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Telephone: 412-471-8815
Facsimile: 412-471-4094
e-mail: webblaw@webblaw.com

having a non-physiological proliferative capacity. Not only are several PCR products described in the specification which are composed of PLAG1 and CTNNB1 sequences which demonstrate that PLAG 1 fragments may be used to diagnose cells having a non-physiological proliferative capacity, the Examiner has already acknowledged, at page 7, lines 6-7 of the Office Action, that that there is adequate written description of SEQ ID NO: 116 which is recognized as having a specific diagnostic function. Moreover, notwithstanding Applicants' discovery that PLAG1 fragments, as recited in amended claim 47, may include the sequences represented in SEQ ID NOs: 117 to 123, Applicants also have discovered at page 5, lines 1-3, that the significance of SEQ ID NO: 116 is even broader still. Applicants disclose that PLAG1 breaks occurring outside the actual genes but in the vicinity thereof result in aberrant growth, so that one skilled in the art will always be able to practice the invention when using at least the claimed nucleic acid sequence corresponding to SEQ ID NO: 116, or a fragment thereof, which SEQ ID NO: 116 is the common denominator of all of the embodiments of the present invention. Therefore, based on the above, as well as because the promoter region of the CTNNB1 gene is known (as set forth in amended claim 48) Applicants submit that the number and predictability of the nucleic acids embraced by the language of newly amended claims 28, 33, 47 and 48 are well defined and adequately satisfy the written description requirement.

For all the foregoing reasons, amended claims 28, 29, 33, 47, 48 and new claims 50-52 are now in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 28, 29, 32-35, 47, 48, and 50-52 is respectfully requested.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By 

Barbara E. Johnson
Registration No. 31,198
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Telephone: 412-471-8815
Facsimile: 412-471-4094
e-mail: webblaw@webblaw.com